

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Additional Instructions for Preparing Institutional National Research Service Award Applications

A. Introduction

This section includes: additional instructions to be used when applying for a competing (new, competing continuation, and supplemental) PHS Institutional National Research Service Award (NRSA); substitute form pages for the table of contents and both budget pages; and instructions for the Research Training Program Plan. Begin by reading the general instructions (on pages 5-6) and then follow both sets of instructions using the Guide for Preparing an Institutional NRSA Application, provided on page V-8.

Prior to preparing an application, consult with the appropriate PHS awarding component. Also review the NRSA Information Statement, noting especially the eligibility requirements, award provisions, payback provisions, and review criteria. The statement can be obtained from GrantsInfo, National Institutes of Health (NIH), (301) 435-0714, e-mail: GrantsInfo@nih.gov. Program announcements, which are issued periodically in the *NIH Guide for Grants and Contracts*, are available from the appropriate PHS awarding component, from grantee offices of sponsored programs or equivalent offices, or from the NIH grants Web site. **The training grant director must explain the terms of the payback service requirement to all prospective postdoctoral training candidates.** A complete description of the service payback obligation is available in the NRSA Information Statement.

B. Specific Instructions

1. Face Page (AA)

Item 2. Response to Specific Request for Application (RFA) or Program Announcement (PA).

Indicate "Institutional National Research Service Award" and include the specific PHS awarding component and specialized program area, if applicable.

Item 4. Human Subjects. If the applicant organization has an approved Assurance of Compliance on file with the Office for Protection from Research Risks (OPRR) but, at the time of application, plans for the involvement of human subjects are so indefinite that Institutional Review Board (IRB) review and approval are not feasible, check "Yes" and insert "Indefinite" at Item 4a. If an award is made, human subjects may **not** be involved until a certification of the date of IRB approval or a designation of exemption has been submitted to the PHS awarding component.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IRB review of human subjects is already complete or an exemption is already designated. This review or exemption designation is sufficient, provided the IRB determines that the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation. If space is insufficient in Item 4, indicate at 4a "Sec. f," and provide the information under the Research Training Program Plan.

Item 5. Vertebrate Animals. If the applicant organization has an approved Animal Welfare Assurance on file with the Office for Protection from Research Risks (OPRR) but, at the time of application, plans for the involvement of vertebrate animals are so indefinite that Institutional Animal Care and Use Committee (IACUC) review and approval are not feasible, check "Yes" and insert "Indefinite" at Item 5a. If an award is made, vertebrate animals may not be involved until a verification of the date of IACUC approval has been submitted to the PHS awarding component.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IACUC review is already complete. This review is sufficient, provided the IACUC determines that the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC review dates. If space is insufficient in Item 5, indicate at 5a "Sec. g," and provide the information under the Research Training Program Plan.

Item 6. Dates of Entire Proposed Period of Support. The usual starting date for an institutional NRSA is July 1, but there are other possible starting dates. Consult the review and award schedule on page 21 in the general instructions. A few PHS awarding components restrict receipt and review dates to once a year. **Applicants are strongly encouraged to contact appropriate awarding component staff before submitting an application.**

2. Description, Performance Sites, and Key Personnel (Form Page 2-BB)

Description. Summarize the essence and major features of the program. Include research areas and disciplines, levels of training, numbers and background experience of trainees, anticipated duration of training, and primary facilities.

3. Table of Contents (Form Page 3-NN)

Use the substitute Table of Contents page (NN) in this addendum.

4. Detailed Budget for Initial Budget Period (Form Page 4-OO)

Use the substitute pages (OO and PP) in this addendum and follow the instructions below.

Refer to the NRSA Information Statement or consult the PHS awarding component for current allowable costs and stipend levels.

Provide information where possible on the substitute Form Page OO, with additional details starting in the budget justification block on substitute Form Page PP.

Stipends

Enter the number of trainees and total stipend amount for each trainee category as appropriate. If a category contains different stipend levels, e.g., for varying levels of postdoctoral experience and/or varying appointment periods, itemize. Enter the total stipends for all categories.

Tuition, Fees, and Self-only Health Insurance

Explain in detail the composition of this item. Itemize tuition, individual fees, and medical insurance. If tuition varies, e.g., in-state, out-of-state, student status, identify these separately. Tuition at the postdoctoral level is limited to that required for specified courses. Tuition and fees (including self-only health insurance) may be requested only to the extent that the same resident or nonresident tuition and fees are charged to regular non-Federally supported students.

Trainee Travel

State the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested, bearing in mind that PHS policy requires less than first-class air travel be used. Justify foreign travel in detail, describing its importance to the training experience.

Training Related Expenses

Funds to defray other costs of training, such as staff salaries, consultant costs, equipment, research supplies, staff travel, etc., are requested as a lump sum based on the predetermined amount, specified in the program announcement, per predoctoral and postdoctoral trainee. Give the number of trainees at each predetermined rate and enter the total dollar figure. No further itemization or explanation is required.

5. Budget for Entire Proposed Period of Support (Form Page 5-PP)

Use the substitute page (PP) in this addendum.

6. Biographical Sketch (Form Page 6-FF)

Include biographical sketches, not to exceed two pages each, for all professional personnel contributing to the training program. Assemble sketches with the program director first and others following in alphabetical order.

7. Other Support (Format Page 7-GG)

Not applicable.

8. Resources (Form Page 8-HH)

Describe the facilities and resources that will be used in the proposed training program. Indicate in what ways the applicant organization will support the program, e.g., supplementation of stipends.

9. Research Training Program Plan

The following instructions are for new and competing applications. If you are preparing a **revised** or **supplemental** application, first see page 14. Then follow the outline suggested below in describing the Research Training Program Plan. **Do not exceed 25 pages of narrative for sections a-d.**

Much of the information requested may be provided in tabular form, which will not be counted toward the page limitation; however, these table pages should be numbered consecutively to maintain the integrity of the application. If tables are placed in the Appendix, they should be numbered consecutively.

Before completing the Training Plan, contact the appropriate PHS awarding component, which may have further advice or suggestions for organizing the relevant data into particular formats.

a. Background

Give the rationale for the proposed research training program, relevant background history, and the need for the research training proposed. Indicate how the proposed program relates to current training activities.

Summarize the research training activities of the major participating unit(s) and department(s) represented in the proposed program. Give the current number of faculty members in each unit and department, as well as the

total numbers of current predoctoral students and postdoctoral trainees.

In a table, list all current and pending training support available to the participating faculty and department(s). Include funding source, complete identifying number, title of the training program, name of the program director, project period, number of training positions (predoctoral and postdoctoral), and amount of the award. For each grant listed, name only those participating faculty members who are also named in this application and indicate their percent effort in those programs.

Table 1

b. Program Plan

(1) Program Direction

Describe the program director's relevant scientific background, research, experience in research training, and qualifications for providing leadership for the program. Indicate the program director's percent of effort in the proposed program.

Describe the administrative structure of the program and the distribution of responsibilities within it, including the means by which the program director will obtain continuing advice with respect to the operation of the program.

(2) Program Faculty

List each training faculty member, his/her primary departmental affiliation, role, and percent of effort in the proposed program.

Table 2A

Describe each faculty member's research that is relevant to this program and indicate how trainees will participate in this research. Current and future research training opportunities should be indicated by providing a **table** that lists, for each participating faculty member, active and pending **research** support. Include all Federal, non-Federal, and institutional research grant and contract support. If none, state "None". Include the source of support, grant number and title, dates of the entire project period, and annual direct costs. If part of a larger project,

Table 2B

identify the principal investigator and provide the above data for both the parent grant and the subproject.

Table 2C

Describe the extent to which participating faculty members cooperated, interacted, and collaborated in the past, including joint publications and joint sponsorship of student research.

Table 3A

In a table, for each faculty member participating in this application, list all past and current students for whom the faculty member has served, or is serving, as thesis advisor or sponsor (limit to past 10 years). For each student listed, indicate: (1) the training level, either predoctoral or postdoctoral; (2) the training period; (3) the institution and degree received prior to entry into training, including date; (4) title of the research project; and (5) for past students, their current positions, and for current students, their source of support. **In competing continuation** applications, mark those trainees who were or are supported by this training grant with an asterisk. Individuals who were trained by proposed participating faculty members at sites other than the applicant organization may be included but should be specifically identified. For **new** applications, list representative recent publications of some of the above students. For **competing continuation** applications, publications of past trainees supported by this grant, provided in the Progress Report of this application, will suffice.

i.e., role (undergraduate, summer student, fellow, predoc, post doc)

Table 3B

(3) Proposed Training

Describe the proposed training program. Give the level and number of trainees. For postdoctoral trainees, provide the proposed distribution by degree (M.D., Ph.D., etc.). Describe course work and research opportunities, the extent to which trainees will participate directly in research, and the duration of training, i.e., usual period of time required to complete the training offered.

Indicate how the individual disciplinary and/or departmental components in the program are integrated and coordinated for the program and for an individual trainee's experience.

For training programs emphasizing research training for clinicians, describe the interactions with basic science departments and scientists. In addition, include plans for ensuring that the training of these individuals will provide a substantive foundation for a competitive research career. Generally, a minimum of 2 years of research training is required for all postdoctoral trainees with health professional degrees. Describe fully any trainee access to and responsibility for patients including percent of effort.

Provide representative examples of programs for individual trainees. Include curricula, degree requirements, didactic courses, laboratory experiences, qualifying examinations, and other training activities, such as seminars, journal clubs, etc. Describe how the preceptor and research problems are chosen, how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated.

(4) Trainee Candidates

Describe recruitment plans, including the sources and availability of trainees. Give the qualifications of prospective trainees and the criteria and procedures by which trainees will be selected.

The size of the applicant and trainee pool and their training progress should be presented **in a table**. For each participating department/unit for each of the past 5 years, give: (1) the number of individuals who have formally applied for training; (2) the number offered admission; (3) the number who entered training; (4) the number who completed or are currently in training; and (5) the number who left the program. Indicate whether

Table 4A

Table 4B-predoc

these individuals were applying for predoctoral or postdoctoral training, and for postdoctoral fellows, give their degrees (M.D., Ph.D., etc.).

The qualifications of prospective **pre-doctoral** trainees and the selectivity of the program should be presented **in a table** which anonymously indicates the credentials and application outcomes of the predoctoral applicant pool for the most recent year for each participating department and unit. For each applicant (identified with a number in sequence, rather than by name, to safeguard privacy), give: the previous institution attended, Graduate Record Examination scores, and grade point average. Indicate whether applicants were or were not offered admission, which applicants matriculated, and whether applicants were U.S. citizens or had permanent resident status.

Table 4B-postdoc

The qualifications of prospective **post-doctoral** trainees in the most recent applicant pool should be presented **in a table** which indicates their: name, degrees and year awarded, previous institution, thesis research topic and preceptor, and residency training when appropriate. Indicate whether applicants were or were not offered admission, which applicants entered the program, and whether applicants were U.S. citizens or had permanent resident status.

c. Recruitment of Individuals from Underrepresented Racial/Ethnic Groups

The policy of the NIH is to promote broad and systematic efforts to recruit individuals from minority groups currently underrepresented in biomedical and behavioral research. NRSA programs are intended to attract and train individuals to pursue independent careers as investigators. Accomplishments of NRSA programs in these areas, with respect to recruiting and retaining individuals from underrepresented groups, will ensure that minority scientists are progressively better represented in the National research effort.

The application must contain information related to the program's plan and experiences in recruiting and training graduate students and/or postdoctoral trainees from racial or ethnic groups, including Blacks, Hispanics, Native Americans, Alaskan Natives, and Pacific Islanders. These groups have been found to be underrepresented in biomedical or behavioral sciences nationally. **Applications without a description of minority recruitment efforts will be considered incomplete and may be returned to the applicant.** The description of such plans and efforts should be arranged as follows:

History

In new applications, describe efforts to recruit minority students into the existing training program. In competing continuation applications, describe past efforts to recruit and retain underrepresented minority students into NRSA training positions.

Achievements

Provide recruitment statistics indicating the number of minority individuals who applied to the program and/or participating units in each of the past 3 years. Give the number of minority candidates offered admission and the number who entered the program. For those who entered the program, indicate their current status, e.g., training, graduated or completed training, and how they were supported. For those who have left the program or completed training, include information about their subsequent career development or employment. In competing continuation applications, indicate which of the minority individuals were supported by the NRSA grant.

Proposed Plans

Describe steps to be taken during the proposed award period regarding the identification, recruitment, and retention of graduate students and postdoctorates from underrepresented groups. Consider the success and/or failures of recruitment strategies used in the past. In particular, describe the specific efforts to be undertaken by the training program and how these might relate to the recruitment efforts of the medical school, graduate school,

Table 5

and/or the university at large. In most cases, institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups.

d. Plan for Instruction in the Responsible Conduct of Research

Every NRSA trainee must receive instruction in the responsible conduct of research, and each training grant application **must** include a description of the plan to provide trainees with formal and informal instruction on scientific integrity and ethical principles in research. Institutions are encouraged to incorporate this instruction into the training of other non-NRSA supported pre- and postdoctoral trainees.

Review of applications lacking a plan for instruction in the responsible conduct of research may be delayed until a plan is provided.

There are no specific curriculum or format requirements for this instruction; however, conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, and data management are areas that are strongly suggested for consideration.

The plan must address the format and subject matter of the instruction and the frequency and degree of participation of the trainees and faculty that are expected. A rationale for the proposed plan of instruction must be provided. For **competing** continuation applications, progress reports on the type of instruction provided, the degree of student participation, and other relevant information will be required.

e. Progress Report (Competing Continuation Applications Only)

Briefly describe the accomplishments of the training program. State the period covered.

Provide a **table** documenting for each year of the current project period, the program's actual assignment of awarded trainee positions. Provide: (1) the total number

of positions awarded in each year; (2) the number of predoctoral trainees appointed ~~and months of support committed~~; and (3) the number of postdoctoral trainees appointed, with what degrees, at what levels, ~~and for how many months~~. Indicate and explain any trainee positions that were not filled.

Provide a **table** listing all trainees who were, or are, supported by this training grant. (Where applicable, provide the data for the past 10 years.) For each student give: (1) the name; (2) the year of entry into the training program; (3) prior institution, and degree at entry; (4) the source of support during each year of training, e.g., this training grant, another (specify) training grant, research grant, university fellowship, individual (specify) fellowship, etc.; (5) the research mentor; (6) the research topic; and (7) for trainees who have completed the program, their current positions and institutional affiliations. Give a brief summary of the research conducted by each trainee supported during the period covered, and list all publications that resulted from the work done during training. Where possible for past trainees, describe the extent of their current involvement in research, including research grant support and representative recent publications. This information will be used to track the pattern of support of trainees and the subsequent research career development of former trainees.

If any postdoctoral trainee with a health professional degree who was appointed to the grant during the most recent award period received less than 2 years of research training, explain why. This explanation should appear in the narrative section of the Progress Report.

Describe any specific effects of this training program on curriculum and/or research directions.

Describe how the funds provided under Training Related Expenses were utilized to benefit the program.

Table 6B

Table 6A

f. Human Subjects

As indicated earlier in these instructions for Item 4 on the Face Page, where appropriate include a list of already reviewed research project grants and their IRB review dates or exemption designations.

g. Vertebrate Animals

As indicated earlier in these instructions for Item 5 on the Face Page, where appropriate include a list of already reviewed research project grants and their IACUC review dates.

10. Appendix

Appendix material is generally not needed with training grant applications. Oversized documents, brochures, and catalogues may be exceptions. If tables or other materials are included, the pages should be numbered consecutively. Five collated sets should be submitted.

11. Checklist (II)

Inventions and Patents. Not applicable.

Facilities and Administration (Indirect) Costs.

Facilities and Administration (F&A) costs under institutional NRSAs, other than those issued to State or local government agencies, will be awarded at 8 percent of total allowable direct costs (exclusive of tuition and related fees). Equipment is also excluded from the F&A costs on those training grants, where Training Related Expenses are not calculated on a lump-sum basis, such as the MARC Honors Undergraduate Research Training Program. State and local government agencies will receive awards at their full F&A cost rate.

12. Personnel Report (JJ)

Not applicable.